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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,053	09/08/2003	Anna P. Catania	54275.8005.US03	3809

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
06/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,053	CATANIA ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-2-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 5-2-07 has been entered.

2. The indicated allowability of claims 1-40 is withdrawn in view of the newly discovered reference(s) to Lipton et al. Rejections based on the newly cited reference(s) follow.

Specification

3. The abstract of the disclosure is objected to because The use of the trademark Carbabol has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 20, 31, 34, 41, 42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim s 4, 20, 31, 34, 41 and 42 contains the trademark/trade name Carbopol. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an acrylic acid-based polymer and, accordingly, the identification/description is indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with

this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,232,804 in view of Borgman (US 4837378).

The claims are drawn to pharmaceutical composition comprising a KPV dimer, first preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

The US patent claims a pharmaceutical composition comprising KPV dimer, a therapeutically effective amount of a anti-inflammatory agent wherein the combination of a KPV polypeptide and the anti-inflammatory agent is effective for treatment of contact dermatitis (see claim 1) The Patent claims claims a composition in the form of a gel (see claim 4). The difference between the US patent and the instant claims is that the US patent does not teach the composition claimed that includes preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

However, Borgman et al. teach formulation, in the form of a gel, for the treatment of dermatitis (see col. 3, lines 20-26). The reference states that gel posses the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients (see col. 21-25). The reference specifically discloses the use of carbopol 940 as the gel forming polymer (see col. 4, lines 53-68 and col. 5, lines 1-2). The composition includes a penetration enhancer that promotes penetration of the active drug into the patients skin or tissue. These include DMSO or propylene glycol (see col. 5, lines 23-31). The composition includes preservatives, such as a mixture of methyl

paraben and propyl paraben, in an amount effective for inhibiting growth of microbes such as yeast and molds during storage (see col. 5, lines 33-42). Further, ethylenediaminetetraacetic acid (EDTA) or one of its salts is commonly added to dermatological preparations, and may optionally be incorporated into the compositions of the present invention. EDTA chelates certain metals that may be present in the formulation, which is useful because some patients have adverse reactions to preparations containing metal impurities (see col. 5, lines 44-55). Finally, the final pH value of the formulations of the invention may vary within a physiologically compatible range. Advantageously, the final pH value is a physiologically compatible, i.e., not harmful to biological tissue, acidic pH value. The pH value is preferably between about 3 and about 6.9, and most preferably between about 4 and 5. Any suitable method of adjusting the pH value of aqueous solutions may be used. Advantageously, sodium hydroxide (NaOH) is added to the composition to bring the final pH value to the desired level. Gel compositions of the invention are more viscous at pH values that approach neutrality than at the more acidic pH values within the preferred range, i.e., viscosity increases as the polymer in the gel is neutralized to a greater degree, e.g., with NaOH (see paragragph bridging col. 5-6). Note that the non-active agent utilized in the reference are identical to those claimed in claim 41-42 of the instant application. Since the US patent claims KPV dimer formulation in the form of gels, it would have been obvious to one of ordinary skill in the art to use the non-active agents disclose in Borgman because of the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients.

6. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7,115,574 in view of Borgman (US 4837378).

The claims are drawn to pharmaceutical composition comprising a KPV dimer, first preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

The US patent claims a composition for the treatment of sinusitis comprising a therapeutically effective amount of a peptide having a C-terminal amino acid sequence KPV selected from the group of peptides consisting of KPV (SEQ ID NO: 1), VKP-Ac-CC-Ac-KPV (SEQ ID NO: 4), HFRWGKPV (SEQ ID NO: 2) and SYSMEHFRWGKPV (SEQ ID NO: 3) in combination with a therapeutically effective amount of a decongestant/antihistamine (see claim 1). Note that the peptide VKP-Ac-CC-Ac-KPV is the KPV dimer as claimed in the instant application. The difference between the US patent and the instant claims is that the US patent does not teach the composition claimed that includes preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

However, Borgman et al. teach formulation, in the form of a gel, for the treatment of dermatitis (see col. 3, lines 20-26). The reference states that gel posses the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients (see col. 21-25). The reference specifically discloses the use of carbopol 940 as the gel forming polymer (see col. 4, lines 53-68 and col. 5, lines 1-2). The composition includes a penetration enhancer that promotes penetration of the active drug into the patients skin or tissue. These include DMSO or propylene glycol (see col. 5, lines 23-31). The composition includes preservatives, such as a mixture of methyl paraben and propyl paraben, in an amount effective for inhibiting growth of microbes such as yeast

and molds during storage (see col. 5, lines 33-42). Further, ethylenediaminetetraacetic acid (EDTA) or one of its salts is commonly added to dermatological preparations, and may optionally be incorporated into the compositions of the present invention. EDTA chelates certain metals that may be present in the formulation, which is useful because some patients have adverse reactions to preparations containing metal impurities (see col. 5, lines 44-55). Finally, the final pH value of the formulations of the invention may vary within a physiologically compatible range. Advantageously, the final pH value is a physiologically compatible, i.e., not harmful to biological tissue, acidic pH value. The pH value is preferably between about 3 and about 6.9, and most preferably between about 4 and 5. Any suitable method of adjusting the pH value of aqueous solutions may be used. Advantageously, sodium hydroxide (NaOH) is added to the composition to bring the final pH value to the desired level. Gel compositions of the invention are more viscous at pH values that approach neutrality than at the more acidic pH values within the preferred range, i.e., viscosity increases as the polymer in the gel is neutralized to a greater degree, e.g., with NaOH (see paragragph bridging col. 5-6). Note that the non-active agent utilized in the reference are identical to those claimed in claim 41-42 of the instant application. Since the US patent claims KPV dimer formulation in the form of gels, it would have been obvious to one of ordinary skill in the art to use the non-active agents disclose in Borgman because of the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

6/25/07

ANISH GUPTA
PRIMARY EXAMINER